UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE GENZYME CORP. SECURITIES LITIGATION	Consolidated Case No. 09-cv-11267 (GAO)
	Leave To File Granted On May 18, 2012

PLAINTIFFS' REPLY BRIEF IN SUPPORT OF MOTION FOR RELIEF FROM FINAL JUDGMENT UNDER RULE 59 AND FOR LEAVE TO FILE PROPOSED FIRST AMENDED CONSOLIDATED COMPLAINT UNDER RULE 15(a)

Plaintiffs submit this reply brief to correct certain statements made by Defendants in their submissions in opposition to Plaintiffs' motion for relief under Fed. R. Civ. P. Rule 59 from the Court's final judgment and for leave pursuant to Fed. R. Civ. P. Rule 15 (a) to file their proposed First Amended Consolidated Complaint (the "PAC").

I. PLAINTIFFS COULD NOT HAVE CREDIBLY SUBMITTED THEIR NEW FACTS TO THIS COURT PRIOR TO THE COURT'S FINAL JUDGMENT ON MARCH 30, 2012

Genzyme suggests that Plaintiffs made a purposeful, strategic decision to withhold new factual evidence until after the Court ruled on the motion to dismiss. *See* Defendant Genzyme's Opposition To Plaintiffs' Motion For Relief From Final Judgment Seeking Leave To File Amended Complaint, at 8-11 ("Genzyme Br."). Genzyme simply is wrong. Plaintiffs did not contact any of the thirteen new witnesses referenced in the PAC until after the oral argument on January 26, 2011, and contacted three of those thirteen (CWs 7, 9, and 15) only after the Court issued its dismissal Order on March 30, 2012.

Rather than being dilatory, Plaintiffs appropriately waited to move to amend until they had obtained sufficient evidence that, considered *cumulatively,* would materially add to the weight of the scienter allegations contained in the first consolidated complaint. *Cf. Tellabs, Inc.*

v. Makor Issues & Rights, Ltd., 551 U.S. 308, 326 (2007) (noting that scienter allegations must be considered "holistically"). Thus, the testimony of the new Confidential Witnesses, taken together, materially strengthens the strong inference of scienter that the CGMP problems were common knowledge at the Allston plant that defendants closely monitored conditions there in the wake of the October 483, and that they monitored the FDA's inspections. (PAC ¶¶15, 46-47, 50-54, 59, 68, 74, 79-82, 84, 87, 90-91, 147, 158). Where problems are common knowledge within a company, it is appropriate to infer that the problems were known to management. *See In re Flag Telecom Holdings, Ltd. Sec. Litig.*, 352 F. Supp. 2d 429, 467 (S.D.N.Y. 2005) (scienter inferred where improper practice is "common knowledge"); *In re Sunbeam Sec. Litig.*, 89 F. Supp. 2d 1326, 1338 (S.D. Fla. 1999) (scienter inferred where improper practice is "common knowledge" and "joked about"); *In re McKesson HBOC Inc. Sec. Litig.*, 126 F. Supp. 2d 1248, 1274 (N.D. Cal. 2000) (widespread company knowledge of improper practice and resistance to change is "highly probative of scienter"). Here, no one witness, standing alone, could provide evidence of "common knowledge," and Plaintiffs could not have credibly moved to amend after each new witness interview.[1]

Defendants' argument ultimately boils down to the position that each time a plaintiff locates and obtains evidence from a new witness, the plaintiff must move to amend or waive its ability to ever do so. However, such seriatim amendments would be impractical and cause an enormous burden for a district court, which would have to address repeated motions to amend and inevitable repeated motions to dismiss complaints. Plaintiffs acknowledge that it is appropriate for a Court to dismiss a complaint with prejudice where a plaintiff has had at least

[1] The information provided by the new CWs is not duplicative of the initial Complaint. That Complaint, by comparison, had only three statements from former Allston employees (one of whom departed in 2004), and there were no statements from witnesses who were aware of the conduct of the Individual Defendants.

one prior opportunity to amend (or where there is no reason to believe that the complaint's defects could be cured). However, it is customary for district courts to grant plaintiffs at least one opportunity to replead fraud claims with additional particularity, especially in light of the unique and heightened pleading standards applicable to claims brought under the PSLRA where a court may hold that a "plausible" claim does not tip the "totality of the circumstances" scale. *See, e.g., George v. Nat'l Watermain Cleaning Co.*, 10-cv-10289-NMG, 2011 WL 841226, at *13 (D. Mass. Mar.7, 2011) (quoting *N. Am. Catholic Educ. Programming Found., Inc. v. Cardinale*, 567 F.3d 8, 16 (1st Cir. 2009)) ("'For deficiencies under Rule 9(b), leave to amend is often given, at least for plausible claims'") (permitting third amended complaint to add details required for RICO claim); *ATSI Commc'ns, Inc. v. Shaar Fund,* 493 F.3d 87, 108 (2d Cir. 2007) ("District Courts typically grant plaintiffs at least one opportunity to plead fraud with greater specificity when they dismiss under Rule 9(b)"). This case law confirms that Defendants' proposed rule, under which Plaintiffs should be required to seek leave to file amended complaints every time they succeed in interviewing a new group of CWs, is unworkable and misguided.

II. DEFENDANTS MISREPRESENT THE ALLEGATIONS OF THE PAC

Plaintiffs allege that in March 2009 Genzyme secretly decided that it would abandon plans to produce Lumizyme for sale in the United States, but did not disclose this decision until July 2009. (PAC ¶¶118-19, 167). Rather than reveal this material information in March, Genzyme continued to project 2009 revenues from U.S. sales of Lumizyme, which they knew would never happen. Defendants also concealed that the reason Genzyme decided not to produce Lumizyme at Allston was that conditions there were so bad that the plant was incapable

of handling the production demands for Lumizyme, which conditions threatened all operations at the plant. *See* Pltf. Opening Br. at 10-11, 18.

In response**,** Genzyme argues that Plaintiffs raised the March 2009 decision as new allegations in the PAC and that the issue only surfaced for the first time during the briefing of Genzyme's motion to dismiss. Genzyme Br. at 19 n. 11. Genzyme is incorrect. The allegation appeared in ¶125 of the initial Complaint filed on March 1, 2010, and Genzyme recognized the import of the alleged nondisclosure by challenging it in its opening brief in support of its motion to dismiss. Plaintiffs discussed the allegations about the March 2009 decision in their opening brief because it appears the Court misapprehended the importance of those allegations to the issue of Defendants' scienter with respect to the BLA: the October 2008 Form 483 had such far reaching implications for senior management that they decided to cease production of Lumizyme for sale in the U.S. *See* Pltf. Opening Br. at 10-11.

Defendants also argue that their public statements were not false because the Company had only decided to halt *production*, but not *sales*, of Lumizyme. *See* Genzyme Br. at 19 n.11. But Defendants confuse two different products: Lumizyme – the 2000L version of Myozyme – was manufactured ***only*** at Allston (for sale outside the U.S., as the FDA had not approved it for use in the U.S.). *See* Compl. ¶52 n.5; PAC ¶36 n.2. Thus, the decision to cease 2000L *production* at Allston necessarily meant that there would be no *sales* of 2000L in the U.S. As Plaintiffs allege, Genzyme decided that instead of ever trying to sell the 2000L product commercially in the U.S., it would rely on the 4000L product – manufactured exclusively at Geel, Belgium and also not yet approved by the FDA – to meet the demand for "mass-producible" forms of Lumizyme in the U.S. *See* Compl. ¶125; PAC ¶119. This information was material to investors because the Belgian 4000L product was even further away from FDA approval than the

Lumizyme (2000L) product manufactured at Allston, thus ensuring months of additional delay before ***any*** revenue from U.S. sales could be expected (and ensuring that Defendants' prior confident predictions of revenue from U.S. sales of 2000L Lumizyme would ***not*** commence in 2009). Thus, Defendants' failure to disclose that as of March 2009, their highly touted Lumizyme BLA was actually – to use Termeer's own words – "a very artificial request to get approval," rendered several of their Class Period statements materially false or misleading. Compl. ¶126; PAC ¶119.

III. THE FEBRUARY COMPLETE RESPONSE LETTER MADE AN EXPRESS LINK TO THE OCTOBER 2008 FORM 483

As Plaintiffs explained, the Court erred when it concluded that the February 2009 Complete Response Letter "did not make any link or connection with the issues mentioned in the Warning Letter or the October 2008 Form 483." Pltf. Opening Br. at 19. Genzyme argues that this Court made no error because "the Complete Response Letter itself …references 'facilities inspections,' but does not reference the Form 483 or Warning Letter themselves." Genzyme Br. at 6. This is incorrect. The Complete Response Letter actually references "deficiencies" that were "conveyed … to the representative of the facility." *See* Fredericks Dec. Ex. 1. The "conveying" refers to the October 2008 Form 483, which was addressed to the then-head of Allston, Kathleen Retterson, *see* McLaughlin Dec. Doc. 64, Ex. A, and a copy sent to Defendant Termeer. Compl. ¶46; PAC ¶91. Contrary to Genzyme's argument, the Court's decision to dismiss the Complaint depended on this misreading of the Complete Response Letter, which the Court repeated several times throughout its Opinion. *See* Pltf. Opening Br. at 6-12.

Defendants' arguments that amending the Complaint would be futile are wrong for the reasons addressed at pages 17-20 of Plaintiffs' opening brief.

IV. CONCLUSION

For the reasons set forth above and in Plaintiffs' opening brief, Plaintiffs respectfully request that their Motion under Rules 59(e) and 15(a) be granted.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Bryan A. Wood, hereby certify that this document, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing, and paper copies will be sent to those indicated as nonregistered participants by first class mail on May 18, 2012.

Dated: May 18, 2012

/s/ Bryan A. Wood
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